REMARKS

The applicants would like to thank the Examiner for the careful attention given the application in the previous Office Action. Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, 112-123 and 124-125 are pending in the application and currently stand rejected. Claims 126 and 127 have been canceled without prejudice and Applicants reserve the right to prosecute these claims in subsequent filings. Applicants also respectfully traverse all rejections. Applicants believe the pending claims to be patentable and respectfully request reconsideration and allowance.

35 USC section 112

Claims 124-127 stand rejected under 35 U.S.C. section 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 126 and 127 have been canceled without prejudice and Applicants reserve the right to prosecute these claims in the future. Claims 124 and 125 have been amended in order to address the rejections raised. Regarding claim 125, the previous Office Action states that the "amount of cycles that would meet or exceed the amount of cycles that would be expected in the individual's lifetime is indefinite and lacks antecedent basis. The claim has been amended to address the antecedent basis issue. Further, Applicant's suggest that the term in not indefinite in that the number of expected cycles of the particular individual may be determined for the individual using expected lifespan and heart rate information specific to the individual under consideration. Reconsideration of this rejection is respectfully requested.

35 USC section 103

Claims 1-3, 5-7, 9-10, 14, 16-18, 20-22, 24-25, 29, 31-37, 41, 54, 56, 58-60, 62-63, 67-68, 70, 72, 74-76, 78-79, 83-84, 86, 88-92, 96-97, 112-119 and 124-127 stand rejected under 35 U.S.C. section 103(a) as unpatentable over "Balloon-Artery Interactions During Stent Placement: A Finite Element Analysis Approach to Pressure, Compliance, and Stent Design as Contributors to Vascular Injury" by Campbell Rogers, David Y. Tseng, James C. Squire, and Elazer R. Edelman (Rogers) in view of U.S.

Patent No. 5,594,651 to St. Ville (St. Ville) and further in view of U.S. Patent No. 6,381,562 to Keane (Keane). Applicant respectfully traverses the rejection.

In order to establish a prima facia case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references. Second, there must be a reasonable expectation of success for such modification or combination. Finally, the prior art reference or references must teach or suggest all claim limitations. (See MPEP section 2143.03) The motivation to combine or modify a prior art reference in order to make a rejection must be found within the prior art and must not be based on the applicants' disclosure.

Applicants suggest that the combination fails to disclose or suggest all limitations of the rejected claims. As discussed above, claim 1 is directed to a system for analyzing medical devices including a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of at least one vascular system and generates a geometric model of said anatomical feature(s). The system also includes a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and generates a finite element model or mesh representing both of said geometric model of said anatomical feature(s) and said geometric model of said medical device. The system also includes a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, loads data on said anatomical feature(s) and/or said medical device and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction of the vascular system to determine the predicted stresses, strains, and deformations of said medical device due to the interaction of the medical device with the anatomical feature.

With reference to independent claims 1, 16, 31, 54, 70 and 86 as well as dependent claims 3, 18, 56 and 72, the previous Office Action states that Rogers teaches a system for analyzing medical devices comprising a stress/strain analyzer that receives a finite

element model or mesh, material properties of the anatomical feature(s) and a medical device, load data on said anatomical feature(s) and/or medical device and simulates an interaction between said anatomical feature(s) and said medical device. The Office Action further states that St. Ville teaches a geometry generator that receives three dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature and a mesh generator that receives said geometric model which generates a mesh. However, claim 1 recites a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of at least one vascular system which is not disclosed or suggested in St. Ville. St. Ville is directed to a system for analysis of hip implant devices and does not disclose or suggest use with the vascular system. Neither Rogers nor Keane cure this deficiency.

In addition, the previous Office Action states that the combination of Rogers in view of St. Ville does not explicitly teach simulating an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the vascular system but that Keane discloses simulation of at least one dynamic expansion and contraction cycle of the vascular system. Applicants respectfully traverse this assertion. Keane is directed to a system for modeling bio-transport systems which include the circulatory system. Keane also suggests that one may wish to model the human heart and simulate its connection to the circulatory system. As discussed in the previous Office Action, Keane also discusses a driving force for fluid motion traced back to a prime mover, for example, the pumping action of the heart. However, as Keane is directed primarily to fluid flow and bio-transport dynamics, Keane does not expressly disclose the simulation of a dynamic expansion and contraction cycle of the vascular system. This deficiency is not cured by either Rogers or St. Ville. As such, claim 1 is allowable over the cited combination as are claims 16, 31, 54, 70 and 86 which include limitations similar to those discussed above and which are allowable over the cited combination for at least the reasons discussed above. Further, the dependent claims 2-3, 5-7, 9-10, 14, 17-18, 20-22, 24-25, 29, 32-37, 41, 56, 58-60, 62-63, 67-68, 72, 74-76, 78-79, 83-84, 88-92, 96-97, 112-119 and

124-127 that depend from these claims are also allowable over the cited combination for at least these reasons.

Claims 4, 19, 57 and 73 stand rejected under 35 USC section 103(a) as being upatentable over Rogers in view of St. Ville as applied in the previous Office Action to claims 1, 16, 54 and 70, and further in view of U.S. Patent No. 5,880,976 to DiGioia III et al. (DiGioia). As discussed above, the combination of Rogers and St. Ville fails to teach all elements of claims 1, 16, 54 and 70 from which claims 4, 19, 57 and 73 depend, respectively. DiGioia fails to cure the deficiencies of Rogers and St. Ville discussed above and claims 4, 19, 57 and 73 are thus allowable over the cited references.

Claims 8, 23, 61 and 77 stand rejected under 35 USC section 103(a) as being unpatentable over Rogers in view of St. Ville as applied to claims 1, 16, 54 and 70 in the previous Office Action and further in view of "Automated Mesh Generation of an Arterial Bifurcation Based Upon In Vivo MR Images" by Seung Lee et al. (Lee). As discussed above, the combination of Rogers and St. Ville fails to teach all elements of claims 1, 16, 54 and 70 from which claims 8, 23, 61 and 77 depend, respectively. Lee fails to cure the deficiencies of Rogers and St. Ville and claims 8, 23, 61 and 77 are thus allowable over the cited references.

Claims 11-12, 26-27, 38-39, 64-65, 80-81 and 93-94 stand rejected under 35 USC section 103(a) as being unpatentable over Rogers in view of St. Ville as applied to claims 9-10, 24-25, 36-37, 62-63, 78-79 and 91-92 in the previous Office Action and further in view of "Computational Mechanics Moves Ahead" by Peter J. Raboin (Raboin). As discussed above, the combination of Rogers and St. Ville fails to teach all elements of claims 1, 16, 31, 54, 70 and 86 from which claims 11-12, 26-27, 38-39, 64-65, 80-81 and 93-94 depend, respectively. Raboin does not teach or suggest simulating an interaction between anatomical feature(s) and a medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data. As such, Raboin fails to cure the deficiencies of Rogers and

St. Ville and claims 11-12, 26-27, 38-39, 64-65, 80-81 and 93-94 are allowable over the cited references.

Claims 15, 30, 42, 69, 85, and 98 stand rejected under 35 USC section 103(a) as being upatentable over Rogers in view of St. Ville as applied to claims 14, 29, 41, 68, 84, and 97 in the previous Office Action and further in view of "GRIZ Finite Element Analysis Results Visualization for Unstructured Grids User Manual" by Douglas E. Speck and Donald J. Dovey (Dovey). As discussed above, the combination of Rogers and St. Ville fails to teach all elements of claims 1, 16, 31, 54, 70 and 86 from which claims 15, 30, 42, 69, 85, and 98 depend, respectively. Dovey does not discuss modeling of an anatomical feature of a vascular system or simulating an interaction between anatomical feature(s) and a medical device over at least one dynamic expansion and contraction cycle of the vascular system. As such, Dovey fails to cure the deficiencies of Rogers and St. Ville and claims 15, 30, 42, 69, 85, and 98 are allowable over the cited references.

Claims 55, 71, 87, and 120-123 stand rejected under 35 USC section 103(a) as being unpatentable over Rogers in view of St. Ville as applied to claims 54, 70 and 86 in the previous Office Action and further in view of "Failure of All-ceramic Fixed Partial Dentures in vitro and in vivo: Analysis and Modeling" by J.R. Kelly, J.A. Tesk, and J.A. Sorensen (Sorensen). As discussed above, the combination of Rogers and St. Ville fails to teach all elements of claims 54, 70 and 86 from which claims 55, 71, 87, and 120-123 depend, respectively. Dovey is a users manual for finite element analysis using unstructured grids and does not discuss modeling of an anatomical feature of a vascular system or simulating an interaction between anatomical feature(s) and a medical device over at least one dynamic expansion and contraction cycle of the vascular system. As such, Dovey fails to cure the deficiencies of Rogers and St. Ville and claims 55, 71, 87, and 120-123 are therefore allowable over the cited references.

In view of the foregoing, Applicant believes the pending claims to be patentable. Reconsideration and early allowance is sincerely requested.

Respectfully submitted,

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